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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,864	07/13/2001	Robert W. Blakesley	0942.5050002/RWE/AGL	9639

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EXAMINER	
MOHAMED, ABDEL A	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 03/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/903,864	BLAKESLEY ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-10,12-14,16-18,20-27,29,31-37 and 39-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5-10,12-14,16-18,27,29,31-37,39-44 and 202* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT TO AMENDMENT, REMARKS AFTER FINAL, STATUS OF THE APPLICATION AND CLAIMS

1. The amendment and remarks of After Final filed 2/4/05 are acknowledged, entered and considered. In view of Applicant's request claims 1, 5, 6, 12, 13, 20-27, 31 and 40 have been amended, claims 2, 4, 11, 15, 28, 30 and 38 have been canceled and claims 41-44 have been added. Claims 1, 3, 5-10, 12-14, 16-18, 20-27, 29, 31-37 and 39-44 are now pending in the application. The rejections under 35 U.S.C. 112, first paragraph and 35 U.S.C. 103(a) over the prior art of record are withdrawn in view of Applicant's amendment and arguments filed 2/4/05. The Finality of the previous Office action is withdrawn in view of the following new grounds of rejections.

CLAIMS REJECTION-35 U.S.C. § 102(b)

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 7-9, 12, 13, 16, 17, 20-22, 24-27, 29, 31 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Condra (U.S. Patent No. 4,973,551).

The reference of Condra ('551 patent) discloses a method of isolating a protein molecule or a population of protein or peptide molecules by contacting the cells with a matrix such as DE-52 anion exchange column which comprises one or more

lysis/disruption/permeabilization composition or compounds in an amount sufficient to digest (lyses) with proteolytic enzyme, preferably pepsin, disrupt or permeabilize the cells. The isolated cells are separated by gel permeation chromatography, preferably Sephadex S 200 (polysaccharide matrix which is a tube, a bead, and a gel) in a separation buffer comprising one or more detergents. Each preparation is added to the column and eluted with the separation buffer. Thus the reference clearly discloses a composition and an apparatus (column) possessing the above-recited properties (See e.g., col. 4, lines 12 to col. 5, lines 36 and Example I) as directed to claims 1, 3, 7-9, 12, 13, 20-22, 24-27, 29, 31 and 32. On col. 7, lines 17 to 28, the '551 patent states that host cells for cloning, DNA processing and initial expression generally include bacteria. The preferred cloning host is *E. coli*. Vectors can be used to express either prokaryotic or eukaryotic genes in a variety of hosts such as bacteria, blue green algae, yeast cells, insect cell and animal cells. The immunogens may also be expressed in a number of virus systems. Thus, the reference discloses the incorporation of polypeptides into an appropriate expression vector and expressed in appropriate host cell system, and as such, meets the limitations of claims 16 and 17.

With respect to the pore sizes recited in claims 1 and 20 (i.e., the matrix comprises pores having an average size ranging from about 0.1 microns to 1,000 microns in diameter), inherently the diameter is the same as disclosed in the prior art Sephadex matrix because the reference isolates a protein molecule or a population of protein or peptide molecules as claimed in claim 1. Further, the instant specification states that the protein extracted were loaded onto Sepharose column (See e.g., page

48, paragraph 0108 in the instant specification). Thus, the references Sephadex inherently must have the same pore sizes as the claimed because in both situations Sephadex is used. Therefore, in the absence of evidence to the contrary, the claimed method, composition and apparatus thereof disclosed by the reference anticipates claims 1, 3, 7-9, 12, 13, 16, 17, 20-22, 24-27, 29, 31 and 32 as drafted.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5-10, 12-14, 16-18, 20-27, 29, 31-37 and 39-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Condra (U.S. Patent No. 4,973,551) taken with Shah et al (U.S. Patent No. 4,303,530) and Henco et al (U.S. Patent No. 5,652,141).

The reference of Condra ('551 patent) as discussed above discloses a method of isolating a protein molecule or a population of protein or peptide molecules by contacting the cells with a matrix such as DE-52 anion exchange column which comprises one or more lysis/disruption/permeabilization composition or compounds in an amount sufficient to digest (lyses) with proteolytic enzyme, preferably pepsin, disrupt or permeabilize the cells. Thus, clearly suggests the use of enzymes for lysis/disruption/permeabilization composition, and as such meets the limitations of claims 9 and 10. The isolated cells are separated by gel permeation chromatography, preferably Sephadex S 200 (polysaccharide matrix which is a tube, a bead, and a gel) in a separation buffer comprising one or more detergents. Each preparation is added to the column and eluted with the separation buffer. Thus the reference clearly discloses a composition and an apparatus possessing the above-recited properties (See e.g., col. 4, lines 12 to col. 5, lines 36 and Example I) as directed to claims 1, 3, 7-9, 12, 13, 20-22, 24-27, 29, 31 and 32. On col. 7, lines 17 to 28, the '551 patent states that host cells for cloning, DNA processing and initial expression generally include bacteria. The preferred cloning host is *E. coli*. Vectors can be used to express either prokaryotic or eukaryotic genes in a variety of hosts such as bacteria, blue green algae, yeast cells, insect cell and animal cells. The immunogens may also be expressed in a number of

virus systems. Thus, the reference discloses the incorporation of polypeptides into an appropriate expression vector and expressed in appropriate host cell system, and as such, meets the limitations of claims 16 and 17.

With respect to the pore sizes recited in claims 1 and 20 (i.e., the matrix comprises pores having an average size ranging from about 0.1 microns to 1,000 microns in diameter), inherently the diameter is the same as disclosed in the prior art Sephadex matrix because the reference isolates a protein molecule or a population of protein or peptide molecules as claimed in claim 1. Further, the instant specification states that the protein extracted were loaded onto Sepharose column (See e.g., page 48, paragraph 0108 in the instant specification). Thus, the references Sephadex inherently must have the same pore size as the claimed because in both situations Sephadex is used. Therefore, the '551 patent clearly discloses contacting cells with lysis/disruption/permeabilization composition or compound to effect lyses of the cells.

The primary reference of '551 patent differs from claims 1, 3, 5-10, 12-14, 16-18, 20-27, 29, 31-37 and 39-44 in not teaching the use of a pore-containing matrix with the pore sizes as claimed and a kit formulation thereof. However, the secondary reference of Shah et al teaches the use of a filter for removing microaggregates from the blood and blood components having a pore size and/or diameter ranging from 20 to about 400 microns which overlaps with the claimed ranges, and as such meets the limitations of claims 1, 5, 6, 20, 21 and 41-44 (See e.g., cols 1-3). Further, the reference of Henco et al on col. 2 and Figure 1 discloses the use of a device having matrix size from 1 to 50 μm in which the cell immobilized with matrix are lysed using detergent and eluted by

adjusting to high ionic strength subsequent to various washing operations. Thus, the secondary reference of Henco et al clearly teaches the use of an apparatus containing a housing, a pore-containing matrix and a chromatographic resin as directed to claims 21-27, 29, 31 and 32.

Therefore, given the teachings of the primary reference of '551 patent, one of ordinary skill in the art would have been motivated at the time the invention was made to adapt the above scheme of using of a pore-containing matrix having the claimed diameter ranges and an apparatus containing a housing, pore-containing matrix and a chromatographic resin. Further, such features are known or suggested in the art, as seen in the secondary references, and including such features into methods and compositions of isolating a protein molecule or a population of protein or peptide molecules by contacting the cells with a matrix which comprises one or more lysis/disruption/permeabilization compositions or compounds in an amount sufficient to lyse, disrupt or permeabilize the cells of the primary reference of '551 patent would have been obvious to one of ordinary skill in the art to obtain the known and recognized functions and advantages thereof. Because the primary reference of '551 patent possess the properties of requiring that cells are contacted with a matrix which comprises one or more lysis/disruption/permeabilization composition or compounds in an amount sufficient to lyse, disrupt or permeabilize the cells.

With respect to the kit, the secondary reference of Henco et al discloses an apparatus containing a housing, a pore-containing matrix and a chromatographic resin; however, from the cited references, it is conventional and within the ordinary skill in the

art based upon the teachings of the combined references to have such kits/compositions as set forth in claims 33-37 since the combined references teach using these compositions together in the same formulation that would have been found in the claimed composition and/or kits to formulate compositions into a kit format because the claimed kit is tailored for use in claimed apparatus kit formulation comprising the composition claimed. Hence, it would have been obvious to package the composition required for the method into kit format of the well-known commercial expediency of doing so.

Therefore, the combined teachings of the prior art makes obvious the claimed invention because at the time the invention was made based on the combined teachings of the prior art and for the reasons given above; one of ordinary skill in the art would have easily adapted the already known methods and compositions and apparatus comprising kit formulation thereof for use in methods of isolating proteins or peptide molecules and composition thereof by contacting the cells with a matrix which comprises one or more lysis/disruption/permeabilization compositions or compounds in an amount sufficient to lyse, disrupt or permeabilize the cells and a kit formulations thereof. Accordingly, claims 1, 3, 5-10, 12-14, 16-18, 20-27, 29, 31-37 and 39-44 are *prima facie* obvious over the prior art, because it is an obvious modification of the prior art combined teachings of methods, compositions and apparatus comprising kit formulation thereof which are suitable for isolation of protein and peptide molecules from any cellular source including a variety of cells from parasites such as coccidia; absent of sufficient objective factual evidence or unexpected results to the contrary.

CONCLUSION AND FUTURE CORRESPONDENCE

4. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272 0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JON WEBER
SUPERVISORY PATENT EXAMINER

Mohamed/AAM

March 10, 2005